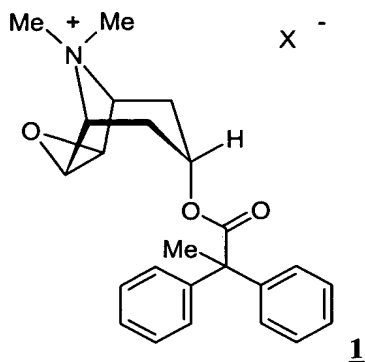


CLAIMS

We Claim:

- 5 1) A pharmaceutical composition comprising one or more anticholinergics of formula 1



wherein

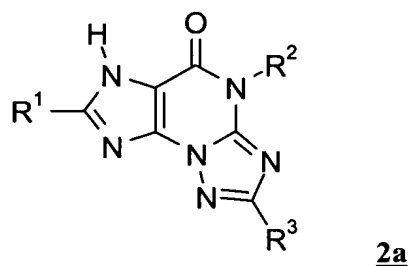
X⁻ denotes an anion with a single negative charge,

- 10 and one or more PDE-IV inhibitors (2), wherein the PDE-IV inhibitor is optionally in the form of an enantiomer, a mixture of enantiomers, a racemate, a solvate or a hydrate thereof,

optionally together with one or more pharmaceutically acceptable excipients.

- 15 2) A pharmaceutical composition according to claim 1, wherein X⁻ denotes an anion selected from chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate.
- 3) A pharmaceutical composition according to claim 1, wherein substances 1 and 2 are present either together in a single formulation or in two separate formulations.

- 4) A pharmaceutical composition according to claim 1, wherein in the compound of formula 1 X⁻ is a negatively charged anion selected from chloride, bromide, 4-toluenesulphonate and methanesulphonate.
- 5) A pharmaceutical composition according to claim 1, wherein in the compound of formula 1 X⁻ denotes bromide.
- 6) A pharmaceutical composition according to claim 1, wherein 2 is selected from enprofylline, theophylline, roflumilast, ariflo, Bay-198004, CP-325,366, BY343, D-4396 (Sch-351591), V-11294A, AWD-12-281, N-(3,5-dichloro-1-oxo-pyridin-4-yl)-4-difluoromethoxy-3-cyclopropylmethoxybenzamide and the tricyclic nitrogen heterocycles of formula 2a



wherein

- 15 R¹ denotes C₁-C₅-alkyl, C₅-C₆-cycloalkyl, phenyl, benzyl or a 5- or 6-membered, saturated or unsaturated heterocyclic ring which contains one or two heteroatoms selected from oxygen and nitrogen;
- R² denotes C₁-C₅-alkyl or C₂-C₄-alkenyl;
- 20 R³ denotes C₁-C₅-alkyl which is optionally substituted by C₁-C₄-alkoxy, C₅-C₆-cycloalkyl, phenoxy or a 5- or 6-membered, saturated or unsaturated heterocyclic ring which contains one or two heteroatoms selected from oxygen and nitrogen; C₅-C₆-cycloalkyl, phenyl or benzyl, each optionally substituted by C₁-C₄-alkoxy,

optionally in the form of a racemate, an enantiomer, a diastereomer, mixtures of enantiomers or diastereomers, a tautomer, or a pharmacologically acceptable acid addition salt thereof.

- 5 7) A pharmaceutical composition according to claim 1, wherein 2 is selected from enprofylline, roflumilast, ariflo, AWD-12-281, N-(3,5-dichloro-1-oxo-pyridin-4-yl)-4-difluoromethoxy-3-cyclopropylmethoxybenzamide and the tricyclic nitrogen heterocycles of formula 2a .
- 8) A pharmaceutical composition according to claim 1, wherein the weight ratios of 1
10 to 2 are in the range from 1:100 to 100:1.
- 9) A pharmaceutical composition according to claim 1, wherein the weight ratios of 1
to 2 are in the range from 1:80 to 80:1.
- 10) A pharmaceutical composition according to claim 1, wherein a single dose for
administration corresponds to a dose of the active substance combination 1 and 2 of 0.01 to
15 10000µg
- 11) A pharmaceutical composition according to claim 1, wherein a single dose for
administration corresponds to a dose of the active substance combination 1 and 2 of 0.1 to
2000µg.
- 12) A pharmaceutical composition according to claim 1, wherein it is in the form of a
20 formulation suitable for inhalation.
- 13) A pharmaceutical composition according to claim 12, wherein it is a formulation
selected from inhalable powders, propellant-containing inhalable aerosols and propellant-
free inhalable solutions or suspensions.
- 14) A pharmaceutical composition according to claim 13, wherein it is an inhalable
25 powder which comprises 1 and 2 in admixture with a suitable physiologically acceptable

excipient selected from monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, salts, or mixtures of these excipients with one another.

15) An inhalable powder according to claim 14, wherein the excipient has a maximum average particle size of up to 250µm

5 16) An inhalable powder according to claim 14, wherein the excipient has a maximum average particle size of between 10 and 150µm.

17) A capsule containing an inhalable powder according to claim 14.

18) A pharmaceutical composition according to claim 13, wherein it is an inhalable powder which contains only substances 1 and 2 as its ingredients.

10 19) A pharmaceutical composition according to claim 13, wherein it is a propellant-containing inhalable aerosol which contains 1 and 2 in dissolved or dispersed form.

20) A propellant-containing inhalable aerosol according to claim 19, containing a propellant gas selected from a hydrocarbon or halohydrocarbon.

15 21) A propellant-containing inhalable aerosol according to claim 19, containing a propellant gas selected from n-propane, n-butane, isobutene, chlorinated and/or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane or cyclobutane.

22) A propellant-containing inhalable aerosol according to claim 20, wherein the propellant gas is TG134a, TG227, or a mixture thereof.

20 23) A propellant-containing inhalable aerosol according to claim 19, wherein it optionally contains one or more other ingredients selected from cosolvents, stabilisers, surfactants, antioxidants, lubricants and means for adjusting the pH.

24) A propellant-containing inhalable aerosol according to claim 19, wherein it contains up to 5 wt.-% of active substance 1 and/or 2.

25) A pharmaceutical composition according to claim 13, wherein it is a propellant-free inhalable solution or suspension which contains a solvent selected from water, ethanol or a
5 mixture of water and ethanol.

26) An inhalable solution or suspension according to claim 25, wherein the pH is 2 - 7.

27) An inhalable solution or suspension according to claim 25, wherein the pH is 2 - 5.
10

28) An inhalable solution or suspension according to claim 26, wherein the pH is adjusted by means of an acid selected from hydrochloric acid, hydrobromic acid, nitric acid, sulphuric acid, ascorbic acid, citric acid, malic acid, tartaric acid, maleic acid, succinic acid, fumaric acid, acetic acid, formic acid and propionic acid or mixtures thereof.

15 29) An inhalable solution or suspension according to claim 25, wherein it optionally contains other co-solvents and/or excipients.

30) An inhalable solution or suspension according to claim 29, containing a co-solvent selected from ingredients which contain hydroxyl groups or other polar groups.

31) An inhalable solution or suspension according to claim 29, containing a co-solvent
20 selected from isopropyl alcohol, propyleneglycol, polyethyleneglycol, polypropyleneglycol, glycolether, glycerol, polyoxyethylene alcohols and polyoxyethylene fatty acid esters.

32) An inhalable solution or suspension according to claim 29, containing an excipient selected from surfactants, stabilisers, complexing agents, antioxidants and/or
25 preservatives, flavorings, pharmacologically acceptable salts and/or vitamins.

- 33) An inhalable solution or suspension according to claim 32, containing a complexing agent selected from editic acid or a salt of editic acid.
- 34) An inhalable solution or suspension according to claim 33 containing sodium edentate.
- 5 35) An inhalable solution or suspension according to claim 32, containing an antioxidant selected from ascorbic acid, vitamin A, vitamin E and tocopherols.
- 36) An inhalable solution or suspension according to claim 32, containing a preservative selected from cetyl pyridinium chloride, benzalkonium chloride, benzoic acid and benzoates.
- 10 37) An inhalable solution or suspension according to claim 29, containing, in addition to the substances 1 and 2 and the solvent, only benzalkonium chloride and sodium edetate.
- 38) An inhalable solution or suspension according to claim 29, containing, in addition to the substances 1 and 2 and the solvent, only benzalkonium chloride.
- 15 39) An inhalable solution or suspension according to claim 25, wherein it is a concentrate or a sterile ready-to-use inhalable solution or suspension.
- 40) An inhaler containing a capsule according to claim 17.
- 41) An inhaler containing an inhalable solution according to claim 25.
- 42) A nebuliser containing an inhalable solution according to claim 39.
- 20 43) A method of treating an inflammatory or obstructive disease of the respiratory tract comprising administering to a patient in need of such treatment a therapeutically effective amount of a pharmaceutical composition according to claim 1.